

Chapter 11 Reprocessing reusable devices in health

11.1 Background

Reprocessing refers to the activities required to ensure that a reusable medical device (RMD) is safe for its intended use. Reprocessing is a multistep process that includes cleaning, inspection and assembly, functional testing (if applicable), disinfection (if applicable), packaging and labelling, sterilization (if applicable) and storage.

Each reusable medical device has specific requirements for reprocessing. Many variables can impact the effectiveness of reprocessing such as device design, reprocessing methodology and methods for validating cleaning and high-level disinfection or sterilization.

RMD technology is constantly evolving and reprocessing requires precision, quality systems, ongoing training and competency of all health workers involved, and compliance to reprocessing procedures.

The Health Organisation undertaking reprocessing of RMDs must:

- have appropriate governance around the management of RMDs including a quality management system in accordance with *AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities*, Australian Commissions Safety Advisory notices and NSW Health policies, guidelines and standard operating procedures
- ensure that health workers responsible for the reprocessing of RMDs within a facility have relevant qualifications and experience in reprocessing
- ensure that they have the facilities, equipment, and easy access to manufacturer-specified cleaning, disinfection/sterilization agents
- ensure that the manufacturers' instructions for use (IFUs) and local procedures are followed
- RMDs, reprocessing agents including hospital grade disinfectants, instrument grade chemical disinfectants, sterilising products and technologies that are used in Health Organisations are listed on the Australian Register of Therapeutic Goods (ARTG) for reprocessing RMDs
- check for microbicidal effectiveness and compatibility of reprocessing agents and chemical disinfectants with the device, and validate
- ensure that appropriate PPE is worn by health workers when reprocessing RMDs
- disinfectants and sterilising products should only be used for their approved purpose
- prior to purchase, obtain a copy of the Therapeutic Goods Administration (TGA) listing or registration certificate. This should be carried out by the health workers involved in the purchase or use of disinfectants or sterilising products (refer to [NSW Health Procurement \(Goods and Services\) Policy Directive](#)). [Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilant](#), [Australian Register of Therapeutic Goods](#)
- after reprocessing RMDs, store in accordance with *AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities* - Handling, transport and storage of released reprocessed RMDs/other devices.

11.2 Reprocessing categories

RMDs and other devices in health are to be reprocessed based on Spaulding's classification. The Spaulding classification system classifies a medical device as critical, semi-critical or non-critical based on risk to patient safety from device contamination. The system categorises medical equipment and devices according to their intended use and the subsequent level of reprocessing required to render them safe for reuse. Table 47 outlines these categories and includes examples of equipment and devices for each category.

Critical and semi-critical RMDs should be reprocessed in a designated reprocessing environment. However, it is not uncommon for a non-critical, usually non-invasive, RMDs to be reprocessed at the point of use.

Whatever the reprocessing method may be, appropriate validation and control of cleaning, disinfecting, packaging and sterilization is essential for reducing the transmission risk associated with the use of RMDs.

Appropriate infrastructure and resources are required to ensure effective and safe reprocessing activities, for example, provision and validation of water and steam quality; trained and competent sterilising technicians; and defined and documented work procedures.

Table 47 Reprocessing categories and processes

Level of risk	Process	Examples of items (lists are not exhaustive)
Critical		
An RMD or other device that have contact with the vascular system or sterile tissue. Must be sterile at the time of use.	Clean as soon as possible after use with a detergent solution. Sterilize by moist heat after cleaning. If RMD is heat or moisture sensitive, sterilize using an alternative process.	Surgical instruments, diagnostic and interventional radiology catheters, cystoscopes, arthroscopes, biopsy forceps, bronchoscopes, cardiac catheters, duodenoscopes, ERCP scopes, dental hand pieces, ultrasonic scalers, cardiac and renal intraoperative probes*
Semi-critical		
An RMD or other device that have contact with mucous membranes or non-intact skin.	Clean as soon as possible after use with a detergent solution. Sterilize by moist heat after cleaning. If RMD is moist heat sensitive, use a low temperature sterilization process or thermal disinfection or disinfection	One-way breathing valves, pneumotachograph screens, mouth shutters, respiratory/sleep therapy equipment, laryngoscope blades, vaginal ultrasound transducers, colonoscopes, gastroscopes, nasoendoscopes specula, ultrasound probes used on non-intact skin

	using a high-level instrument grade chemical disinfectant.	
Non-critical		
An RMD or other device that only have contact with intact skin and not mucous membranes.	Clean as soon as possible after use with a detergent solution. If necessary, disinfect with compatible low-level or intermediate-level disinfectant after cleaning.	Bedpans, commodes, EEG and ECG leads, blood pressure cuffs, beds, thermometers, SaO2 probes and stethoscopes.

* Intraoperative probes that will have contact with sterile tissue or the vascular system.

11.3 Reprocessing methods

In accordance with AS 5369:2023, the three usual methods for reprocessing are defined as:

- **Cleaning:** The removal of contamination from an item to the extent necessary for further processing or intended use
- **Disinfection:** Process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose
- **Sterilization:** A validated process used to render a product free from viable microorganisms.

11.3.1 Cleaning

Reprocessing begins with processing at the point of use, such as, proximity to the point of use of the device to facilitate subsequent cleaning steps. The point-of-use processing includes prompt, initial cleaning steps and/or measures to prevent drying of organic material and contaminants in and on the device.

Thorough cleaning and removal of contaminants by manual or automated systems is essential for further processing either by disinfection (thermal or chemical) and sterilization of RMDs. Residual contaminants (organic or inorganic) on the RMD surface can interfere with the effectiveness of these processes.

Instruments are to be cleaned either by hand and/or mechanically, following both manufacturer's instructions for use (IFUs) and the requirements set by *AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities* to assist with identifying the level of reprocessing required.

If the device has removable parts, then reprocessing instructions must include step by-step instructions for disassembly and reassembly of the device to facilitate cleaning and reprocessing. The equipment needed to perform these activities must be identified and provided to health workers performing these tasks. For easy access to information diagrams, photographs, illustrations and/or videos on manufacturer's instruction for use (IFU) are recommended. In addition, the instructions should indicate the location where this step should be performed (for example, at the point of use, at the designated cleaning area).

Disassembly and reassembly instructions must be explicit, device-specific, and concurrent with the validation activities. Health workers performing these tasks must be trained, competent and qualified. The cleaning process must be validated and at a minimum by visual inspection.

For cleaning of RMDs, IFU often recommends a neutral or near-neutral pH detergent solution because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material by attacking proteins that make up a large portion of common soil (for example, blood). Enzyme solutions should be used in accordance with manufacturer's IFU, which include proper dilution of the enzymatic detergent and contact with equipment for time specified on the label.

The cleaning process should flow in one direction from dirty/contaminated to clean and, ideally the reprocessing of the RMDs should be in a dedicated area if not well clear of the contaminated zone.

11.3.2 Disinfection

Disinfection (thermal or chemical) of RMDs kills many pathogenic microorganisms. However, unlike sterilization, disinfection is not effective against high numbers of bacterial spores. Many factors affect the efficacy of a disinfecting process, such as, presence of soil, nature and level of microbial contamination, RMD design, concentration of disinfectant, temperature and exposure time, pH levels and presence of biofilm. Therefore, users should read labels carefully to ensure the correct product is selected for the intended use and applied to meet maximum efficacy.

Chemical disinfectants vary significantly in their antimicrobial abilities and speed of action. Specifically:

- low-level disinfectants kill most vegetative bacteria (except *Mycobacterium tuberculosis*), some fungi and inactivate some viruses
- intermediate-level disinfectants kill vegetative bacteria including mycobacterium species, viruses and all fungi and inactivate most viruses but do not kill bacterial spores
- high-level disinfectants kill all microorganisms except for high numbers of bacterial spores. Some disinfectants used as high-level disinfectants are capable of sterilization with prolonged exposure, under controlled and defined conditions.

RMDs that require exposure to a disinfection process must have been categorised as semi-critical or non-critical according to Spaulding classification (*AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities*).

Semi-critical RMDs:

- must be sterilised by either validated moist heat or low temperature sterilising process between uses on individual patients unless RMD is not compatible with these processes
- that are not compatible with sterilization must be subject to a validated thermal disinfection process between uses on individual patients unless RMD is not compatible with this process
- that cannot withstand thermal disinfection process must be subject to a validated high level chemical disinfecting process between uses on individual patients. If this process is also not compatible alternative options such a single use should be sought.

11.3.3 Sterilization

Sterilization destroys all microorganisms on RMDs, rendering them free of viable microorganisms. There are several forms of sterilization, and the selected method must be recommended by the RMD's manufacturer.

Moist heat sterilization is the preferred process of sterilization of RMDs where the item can withstand the high temperature and pressure of this process. If an item cannot withstand a moist heat sterilising process, a suitable and alternative validated process will be necessary.

An alternative form of sterilization may be a low temperature gas, plasma or liquid chemical sterilising process and may also depend on resources available within the Health Organisation.

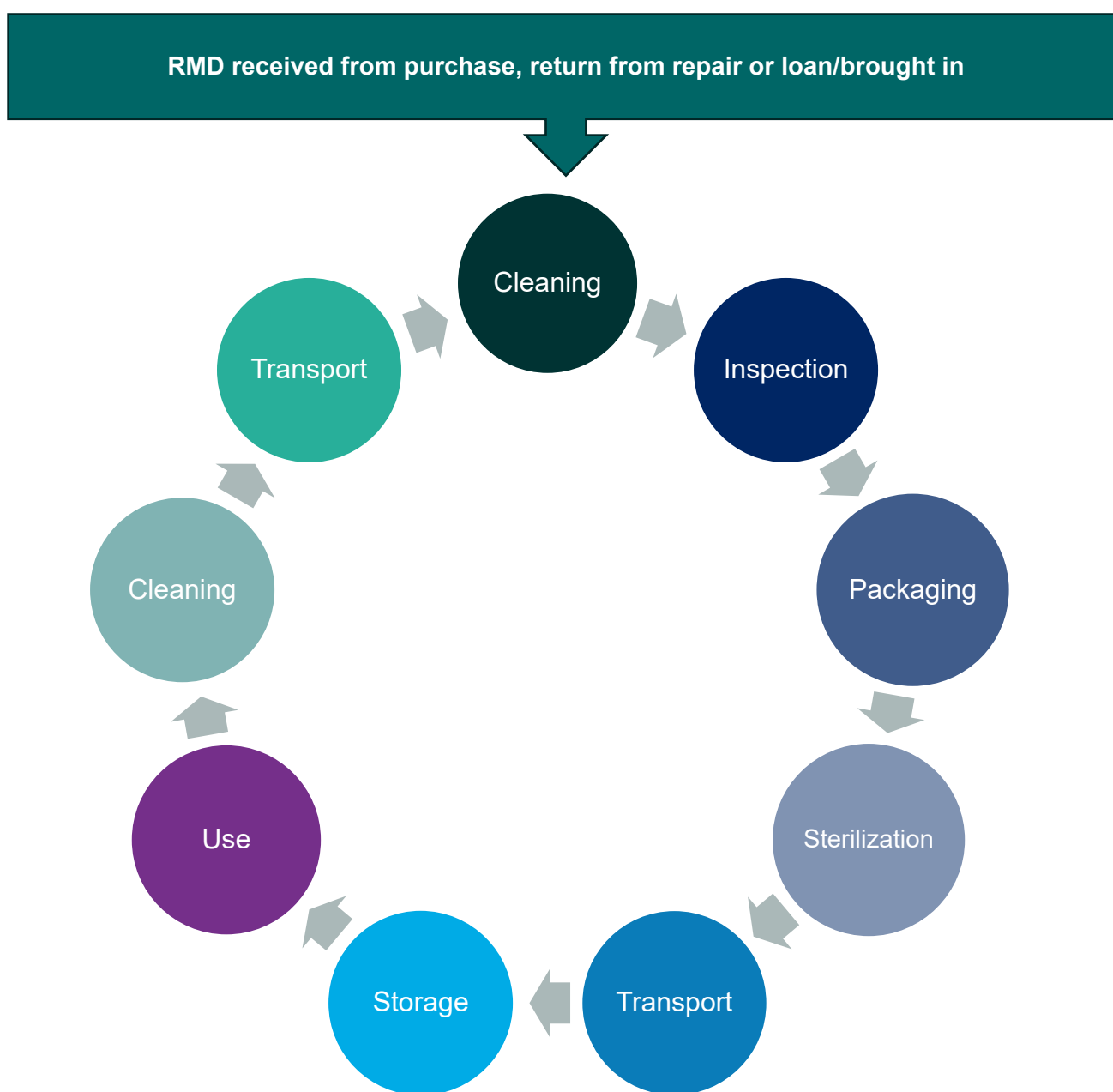
The delivery of sterile products for use in patient care depends on the effectiveness of the sterilization process including the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality, quantity, appropriateness of the cycle for the load contents, and other aspects of device reprocessing.

Ensuring consistency of sterilization practices requires a comprehensive program by Health Organisations that ensures operator competence and proper methods of cleaning and wrapping instruments, loading the sterilizer, operating the sterilizer, and monitoring of the entire process.

11.4 Reprocessing of critical RMDs

Reprocessing of a critical RMD should involve the steps shown in the below figure.

Figure 23 Reprocessing a critical RMD



Note: follow instruction for use as per manufacturers specifications at each step.

11.5 RMDs on loan or brought by clinicians

With the ever-increasing complexity and cost of medical procedures and surgical instruments in general, many Health Organisations utilise loan equipment and loan sets. Loan sets have become an integral part in the care of patients requiring surgical intervention.

In the decision-making process regarding use of loan sets, privately owned RMDs and/or RMDs brought in by clinicians, Health Organisations should identify:

- key stakeholders and their roles and responsibilities, local governance and accountability
- the financial and resource implications, including the capacity to accommodate the volume, complexity, storage and resources required for reprocessing
- Health Organisations must always check for approval for use in Australia, ARTG certificate, manufacturers IFU, local procurement processes and biomedical engineering requirements.

For more information refer to the CEC [Reprocessing of Reusable Medical Devices \(RMDs\) on Consignment or Loan for Use in Surgical, Dental or Other Invasive Procedures](#) guidance document.

All loan transport containers must comply with [Work Health and Safety Regulation 2011](#) and SafeWork NSW guide on [Design and handling of surgical instrument transport cases: A guide on health and safety standards](#).

The supply, packaging, transportation, handling and processing of loan sets must be undertaken in a manner that ensures the safety of patients, health workers involved, environmental sustainability and comply with occupational health and safety regulations including:

- the transport containers are to be maintained by the supplier in a clean, dry state and in good working order
- the Health Organisation needs to have a system in place for handling loan equipment that complies with Work Health and Safety Regulation 2011
- the medical team should provide the designated health workers with a full description of the RMDs required to be ordered
- health workers must provide all instructions necessary for the provider to supply the loan sets in a manner that is safe and timely to allow for sufficient time for reprocessing and micro testing, if required
- the scheduling of procedures may be influenced by whether additional reprocessing, education and training requirements need to be met prior to or after reprocessing and the duration of reprocessing required
- suppliers are to send disassembling, cleaning and sterilization/disinfection instructions for multi-component instruments and these instructions should be followed.

Prior to use, loan sets must undergo cleaning and disinfection or sterilization as appropriate for the intended use. This applies to instruments and equipment loaned by sponsors and other Health Organisations, for example, loan sets, borrowed RMDs from private facilities and RMDs used between public facilities, as well as instruments and equipment owned or supplied by individual staff including locums, visiting medical officers and staff specialists.

Prior to reprocessing, health workers must inspect loan set instruments against the supplier documentation of contents on arrival and on return to confirm that the contents are correct and complete and that all appropriate documentation (such as tray lists) is present (NSW Health PD2023_002 [Accountable Items used in Surgery and Other Procedures](#)). Health workers are also to check that the manufacturer's IFU and local procedures for reprocessing are provided and followed.

Health workers are to ensure that loan sets are delivered for use on time and with all required documentation. Perceived lack of time should not permit the cleaning and disinfection or sterilization process to be bypassed.

After use, and before being returned, a loan RMD at a minimum should be processed by a validated cleaning and high-level disinfection process in accordance with the IFU. Any damaged instruments or instruments needing repair should be reported to the provider. Any instruments missing should be reported immediately to the operating theatres. The notification should comply with the NSW Health policy directive [Accountable Items used in Surgery and Other Procedures](#) and [NSW Health Incident Management Policy](#).

Note: reusable loan set instruments used on humans must never be used on animals, or for necropsy or autopsy.

Where a Health Organisation is expected to reprocess clinician owned RMDs or loan sets, the Health Organisation's reprocessing unit is to be provided with the following information when receiving the device/sets:

- manufacturer's name
- name and contact details for manufacturer's local representative
- ARTG certificate or list number
- device manufacturer's IFU
- time requirement for reprocessing, identified risks and control measures if any; and specific training if needed.

Without the provision of this information, local reprocessing units will be unable to adequately reprocess privately owned RMDs or loan sets.

To reduce the risk of damage to privately owned RMDs or loan sets during transit to the Health Organisation, instrument containers should be fit for purpose, packaged and transported in a way that prevents damage; and meet the requirements for manual handling of the Work Health and Safety Regulation 2011.

On receipt at the Health Organisation, the local reprocessing unit should examine the integrity of the container. If the integrity of the container has been compromised the following actions are required:

- decant contents of broken container into an intact container
- remove the broken container from circulation
- reprocess instruments, regardless of whether the contents have been previously reprocessed
- report issues to the sponsor and the TGA.

11.6 Implantable devices

Medical device (other than an active implantable medical device) that is intended by the manufacturer to:

- (a) be, by surgical intervention, wholly introduced into the body of a human being and to remain in place after the procedure
- (b) replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being and to remain in place after the procedure; or
- (c) be, by surgical intervention, partially introduced into the body of a human being and to remain in place for at least 30 days after the procedure.

There are two types of orthopaedic implant:

- 1) Sterile implants (for example, joint prostheses) are distributed sterile ready-for-use

- 2) nonsterile implants (for example, plates, screws, Schanz pins, intramedullary rods) are processed by a healthcare facility's sterile service department (SSD).

Many such implants are classified as single use, according to the manufacturers, and should not be re-used following any contact with a patient.

Orthopaedic implants, such as screws and screw banks, are provided in a non-sterile state and must be reprocessed before each use, therefore they may be subjected to multiple reprocessing cycles until they are implanted in the patient. Health Organisations are to be aware of, and risk assess, the impact of various exposures to physical, chemical and biological agents and this can compromise their quality/safety and promote biofilm formation.

Health Organisations using or managing implantable devices are to ensure that:

- single use devices or items intended for human implantation must not be reprocessed or reused after patient use
- implantable devices used for orthopaedic and dental surgery that are received packaged and sterilised with identification from the manufacturer, should not be opened and used to restock racks or trays
- implantable devices must not be 'flash' sterilised
- manufacturers provide validated cleaning instructions for non-sterile implantable devices
- implantable devices labelled as "single use" are not reprocessed, due to inability to reprocess adequately
- documentation is completed as per [NSW Health Care Records - Documentation and Management](#).

11.7 Management of incidents

Health Organisations that undertake reprocessing of RMDs must have an established system in place to manage incidents of real or suspected failure of cleaning, disinfection or sterilization.

If any item(s) used on a patient are subsequently found to be inadequately disinfected or sterilised and sterility has been compromised, the Health Organisation must establish the risk and determine the extent of the issue.

A risk assessment framework must be used to determine infection prevention and control breaches related to disinfection or sterilization failure. Processing failures relating to items used in patient care must be investigated and managed in accordance with current *AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities*, [Infection prevention and control in Healthcare Settings](#) and [Incident Management](#) policy directive.

Effective management of the recall process requires the traceability of RMDs to patient records by either electronic or manual systems. Traceability is imperative when looking back at the history, location or application of the RMDs that is under consideration.

Where the processing equipment has failed, the equipment under question must not be used again until rectified and satisfactory results are obtained from physical, chemical and/or biological monitoring.

When the processing equipment has been repaired and or rectified, physical and chemical monitoring to be conducted to confirm if the equipment is fit for reuse.

11.8 Education and training

Health workers working in reprocessing areas should understand the principles and practices outlined in Australian standard AS 5369: 2023: *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*. For more information refer to [CEC Assessment of Reprocessing Competencies](#). Health workers who collect microbiological samples of scopes are to complete training in aseptic technique.

11.9 Management of complex and difficult to reprocess RMDs

Reusable medical devices (RMDs) are classified as complex and difficult to reprocess when it is not possible to ensure the effectiveness of cleaning, disinfection, or sterilization. Devices that are difficult to clean often have intricate designs, such as cannulations or internal channels, which present ongoing challenges during decontamination. To ensure effective cleaning:

- The device must be designed to allow physical friction—either through brushing or ultrasonic methods—on all surfaces and enable visual inspection of those surfaces
- RMDs with dead-end lumens should be recognised as particularly difficult to clean
- Reprocessing departments, perioperative teams, and procedure-based facilities should aim to phase out complex and hard-to-reprocess RMDs, replacing them with designs that can be disassembled to facilitate thorough cleaning and reprocessing
- Maintain an up-to-date list of RMDs that are difficult to reprocess and ensure these are documented in the organisation's risk register.

Health Organisations are to adopt a comprehensive risk management approach when making decisions about purchasing, hiring or borrowing medical instruments and equipment to reduce the risks associated with difficult to reprocess RMDs (figure 24 Risk assessment flow chart). Also refer to [CEC General rules for reprocessing complex and difficult to clean devices – video laryngoscopes](#).

Figure 24 Risk assessment flow chart

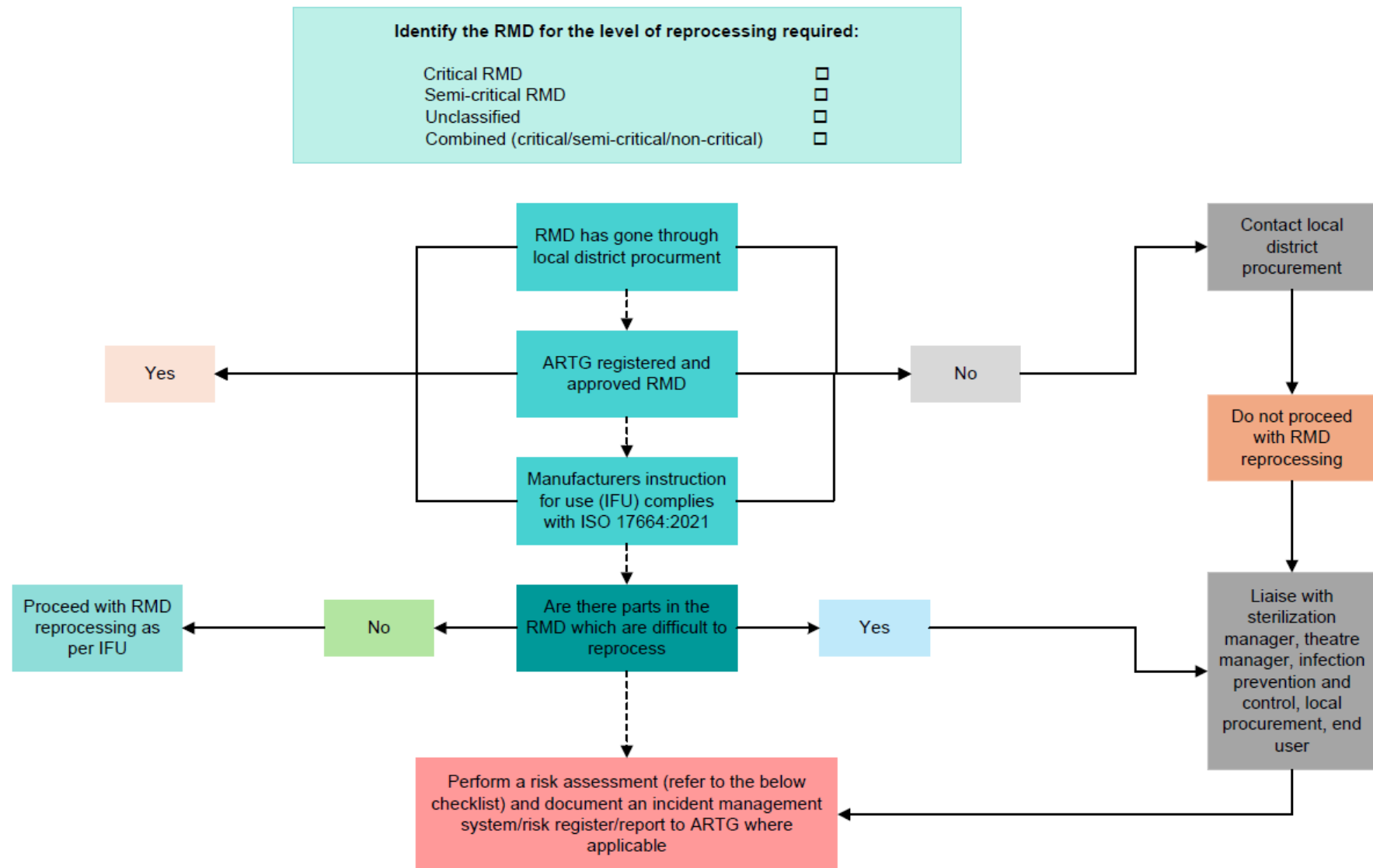


Table 48 Risk assessment checklist for RMDs when IFU does not comply with AS 5369:2023 or RMD identified as difficult to clean

☐ IFU does not comply with AS 5369:2023 ☐ RMD identified as difficult to clean			
Name of the RMD Manufacturer			
Liaise with the following stakeholders to proactively conduct comprehensive risk assessment using the below checklist			
☐ Sterilization services team (local/district) ☐ infection prevention and control ☐ Procurement ☐ End users (for example, surgeon, theatre manager) ☐ Other			
	Yes	No	N/A
Are there alternative methods available for the RMDs to be reprocessed according to AS 5369:2023 to a safe level which minimises infection risks to patients?			
If the answer to the above question 'no', consideration must be given to the following:			
Is the RMD able to be substituted with a more suitable device?			
Is the use of this RMD necessary at the facility?			
Is the non-use of this RMD life threatening to the patient?			
Is there a single use option available for this RMD?			
If there are no alternatives, review the device's IFU to identify: • is it a complex item? • are there correct tools available to assemble/reassemble this RMD? • are there correct solutions available to reprocess this RMD? • is there enough inventory to allow for adequate turn-around time to effectively reprocess the device			
Whether parts and/or the whole device can be sterilised?			
Is there a need for sterile sheath/cover?			
Is there a need for any process change to reprocess this RMD?			
Are there risk mitigation strategies able to be implemented to reduce infection prevention and control risks to patients?			
Staff responsible for reprocessing RMDs are trained to perform all reprocessing steps as per the device's IFU			
Are the risk mitigation strategies implemented and documented?			

Is there a need for this RMD to be reported to ARTG?			
Have you contacted your peer group for input to establish if device use is wide-spread or isolated?			
Incidents of surgical site infections or adverse events associated with procedure or this RMD use has been recorded and reported?			
Comments			
Name Designation Signature Date			

11.10 New technologies

New technologies have made great advancements with beneficial outcomes for patients requiring specialised and complex surgical procedures. Extensive consultation with the reprocessing unit and infection prevention and control is required prior to the purchase of any new technologies.

A risk assessment of the RMD may be required, particularly if the instrument is deemed to be 'difficult to reprocess' (refer to figure 23 and table 48 for further information).

The assessment should consider:

- the design of the instrument:
 - can it be taken apart for thorough cleaning?
 - are there any complex joints that cannot be cleaned adequately?
 - will the design affect the ability to clean over time?
- local capacity and expertise:
 - review the manufacturer's instructions for use (IFU) and reprocessing requirements
 - ARTG listed or registered
 - can optimal and validated reprocessing of this instrument be done in this unit?
 - is this unit equipped to reprocess this instrument?
 - do reprocessing staff need specific training to reprocess this instrument?

Risk assessment outcomes should be reported to the appropriate Clinical Governance delegate for further discussion with the Health Organisation's product selection committee or equivalent.

When new instrumentation is purchased, the Health Organisation to ensure that the manufacturer or their representative provides initial training to health workers. Once initial training has been provided, local trainers are responsible for providing education to other health workers, including new staff.

11.11 Maintenance and repair

RMDs that are to be sent for maintenance or repair must, prior to dispatch, be cleaned and disinfected or sterilised in accordance with the manufacturer's IFU.

On return prior to placing back into circulation for use, these items must be checked or inspected, disassembled if required and reprocessed in accordance with manufacturer's IFU and facility procedures.

11.12 Covers and sheaths

Some RMDs may require a single-use sterile cover or a sheath to protect the instrument or equipment during procedures. When covers or sheaths are used the reusable item(s) must be completely reprocessed between patient procedures.

Covers and sheaths must not be used as a substitute for routine cleaning, disinfection or sterilization of instruments and equipment.

11.13 Quality assurance

Health Organisations are to perform regular periodic audits to confirm that the requirements of AS 5396:2023 are being met. The audit findings are to be documented and, where applicable, corrective action implemented to rectify deficiencies. Corrective actions are to be reviewed to ensure that it has been effective in addressing the deficiency. Health Organisations are to have a formalised and documented process for delivery and pick-up of instruments.

11.14 Reprocessing in Oral Health

The practice of dentistry frequently involves the use of sharp instruments which can pierce skin and mucous membranes during treatment. In dental practice there is a risk of cross-contamination as treatment may involve contact with saliva, blood and endodontic pulp tissue. These and other dental materials may be difficult to remove if allowed to dry.

Effective sterilization of instruments relies on effective cleaning prior to sterilization. Therefore, all visible dental materials should be removed from instruments at point of use to prevent substances drying on these instruments. Formal training in reprocessing of RMDs is required for all personnel who clean and reprocess dental equipment.

Many of the reusable instruments and burs utilised in oral health services are classified as 'difficult to reprocess' and require special attention and cleaning procedure. Refer to the flow chart in figure 23 and table 48 for further information on risk assessment on difficult to reprocess RMDs.

Oral health services utilising a steam sterilizer to sterilize dental equipment within their unit are to follow the requirements for testing, documentation and quality control as specified by AS 5369:2023.

The Dental Board stipulates the expectations for infection prevention and control based on the current edition of the [ADA's](#) Guidelines for Infection prevention and control, NHMRC [Australian Guidelines for the Prevention and Control of Infection in Healthcare](#) and AS 5369:2023.

When RMDs are being reprocessed outside of the oral health service unit, an initial pre-treatment is to be performed at the point of use of all RMDs/other devices before being transported. These items must be contained within a puncture-proof and lidded container for transportation, and the transport vehicle should be temperature controlled.

Surface barriers help prevent contamination of surfaces and equipment. Surface barriers on equipment need to be placed carefully to ensure that they protect the surfaces underneath and should be changed and cleaned between patients. Cleaning clinical surfaces, including equipment, should always occur between patients or uses, regardless of whether a surface barrier has been used or not, any exceptions should be justified by risk assessment ([NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare](#)).

For specialised equipment which is difficult to clean and the application of detergent directly onto the device is not recommended by the manufacturer, a custom surface barrier should be used, for

example, intraoral camera. Any custom surface barrier used on such equipment should be disposed of after each patient treatment and replaced with a new custom surface barrier.

The custom surface barriers are specific to each type of specialised equipment and provided by the manufacturer of that specialised equipment. Health Organisations are not to use other surface barriers on that specialised equipment.

Health Organisations are to have a local policy that describes their specialised equipment and its specific reprocessing.

According to section 5.6.15 of AS 5369:2023, it is important to control temperature and humidity where RMDs are packaged and where sterilised RMDs are being stored.

Where 24-hour air-conditioning control of temperature and humidity of the sterile stock storage area does not occur, the permitted use life of packaged RMDs needs to be set at an appropriate interval, due to degradation of the packaging material, such as at 12 months. For situations where high temperature and humidity conditions exist in sterile storage areas outside of working periods, setting a shorter interval such as three or six months is appropriate. Regardless of where the reprocessing area is located (collocated or standalone), the ventilation, humidity and temperature control within these areas should be managed to ensure the sterility of the items are maintained (ADA). An action plan should be in place to rectify any issues that may arise.

11.15 Intracavity ultrasounds

Intracavity ultrasound transducers (for example, transvaginal, trans-rectal or intraoperative) are to be reprocessed in accordance with the manufacturer's IFU and AS 5369:2023. If an intracavity ultrasound transducer cannot be sterilised, thermal or high-level chemical disinfection is required to minimise the risk of cross contamination and ensure patient safety. Additionally, automation, validation, and traceability of disinfection systems for ultrasound probes are recommended.

Sterile gel and sterile single-use probe covers are also to be used. The use of disposable/sterile covers are not used as a substitute for cleaning, disinfection or sterilization.

Reprocessing cycle records are to be maintained by the Health Organisations with the following information as a minimum:

- transducer serial number
- date and health worker responsible for reprocessing
- method of disinfection; disinfection cycle or load number
- name and signature of the person releasing the transducer for use.

When using chemical disinfectant:

- fume extraction cabinets may be required
- specialised requirements are to be followed during disposal
- approved spill kits are to be available in the reprocessing area in case of spillage
- appropriate PPE is to be worn by health workers when reprocessing ultrasound transducers.

If using chemical disinfection, batch information, preparation date and use by date of the chemical disinfectant should be documented.

Any failed cycles or interruption during the disinfection process are to be documented and the transducer must be fully reprocessed prior to use. In addition, chemical indicators are to be used to

validate concentrations and/or holding time and documented as recommended by the chemical disinfectant manufacturer. To ensure health worker safety and reduce the risk of damage:

- Contaminated ultrasound transducers are to be transported to the reprocessing area immediately after use, in a closed container that can be effectively cleaned and disinfected
- Transport containers are to be thoroughly cleaned and dried between uses
- Reprocessed ultrasound transducers are to be stored in a clean environment to maintain the sterilization or disinfected process.

Each sterilised or disinfected ultrasound transducer is to have an indicator attached to confirm that appropriate reprocessing methods have been followed.

11.16 External ultrasounds

RMDs, including bladder scanners, ultrasound machines and transducers may act as both a source and a vector of potential cross contamination.

Ultrasound transducers used in percutaneous procedures are classified as non-invasive medical devices as the transducer does not penetrate inside the body, either through a body orifice or through the surface of the body. After use it requires cleaning, as per the manufacturer's IFU and depending on the outcome of a risk assessment, low level disinfection (LLD) with an approved and compatible disinfectant.

Ultrasound transducers that penetrate inside the body through areas of non-intact skin (for example, burns sites, open wounds, skin ulcers) or contact areas with mucous membranes (for example, rectum, vagina), are classified as invasive medical devices. Invasive ultrasound transducers are classified as semi-critical devices and require a minimum of high-level disinfection (HLD) before patient use.

If a transducer used for a non-invasive procedure have contact with non-intact skin or body substances during the procedure, it should be reclassified as a semi-critical item. In such cases, high-level disinfection is required, regardless of the use of a protective sleeve/sheath.

For more information refer to [ACSQHC Cleaning and disinfection of ultrasound transducers](#).

Sterile ultrasound gels are packets or sachets that are labelled as sterile and have not been opened. Ultrasound gels that are labelled as non-sterile, or do not reference sterility, are considered non-sterile.

Under certain unfavourable circumstances ultrasound gel can also become contaminated with a variety of microorganisms and cause infection.

Ultrasound gels may be sterile or non-sterile and have been the source of past outbreaks of infection (Angrup et al., 2022, Hudson et al., 2022). Health Organisation are to implement controls to ensure no refilling of bottles, maximum use period despite expiry date to minimise amount of bacterial growth in multi-use gel.

The use of non-sterile gel should be limited to low-risk general examinations on intact skin. The use of reusable containers is discouraged due to the lack of appropriate sinks and drying areas in most facilities.

If a non-sterile gel is being used on a patients, regardless of their infectious disease status, a single-use gel bottle or sachet should be used ([ASA The safe use and storage of ultrasound gel 2022](#)).

Due to the risk of bacterial contamination and growth within a warm environment, heating of gel/s is not recommended. In circumstances where warm gel is necessary, the use of dry heat is the preferred method. After each use, lids should be closed on reusable gel bottles.

As per the [ASUM Guidelines for Reprocessing Ultrasound Transducers](#), the basic minimum standards to minimise the infection transmission risk through the use of contaminated ultrasound gel are as follows:

- always follow the manufacturer's instructions for care and use
- ensure reusable dispenser bottles are completely emptied, thoroughly washed and dried daily/weekly, according to your facility's infection control practices
- clean all reusable equipment according to the manufacturer's instructions
- for procedures that require the use of sterile gel, ensure that only unopened containers/sachets labelled 'sterile' are used
- Any unused portion of single-use sterile gel packets must be discarded and not reused for another examination or patient.

Surface probes used on intact skin and bladder scanners

Following a non-invasive procedure, for example, scanning over intact skin or bladder scan, all gel is to be removed from the probe, and the transducer probe is to be cleaned with a neutral detergent non-residual wipe and, if required, disinfected with an appropriate hospital grade disinfectant in compliance with the manufacturer's IFU and TGA regulations.

After use the cleaning procedure should include the entire cable from the transducer to the machine and extend to the surface of the machine.

If an ultrasound transducer or associated equipment has contact with blood and/or body substance, first clean with a neutral detergent and then disinfect with an appropriate disinfectant in compliance with the manufacturer's IFU and TGA regulations.

Ultrasound devices used on non-intact skin or contact with mucous membrane

Ultrasound transducers used for imaging the vascular system for insertion of venous access devices should be used with a sterile probe cover and sterile gel.

If the probe cable is likely to have contact with a sterile drape, for example, during insertion of a central access device, the cable should be covered with a long sterile sheath and be managed in such a way as to maintain the sterility of the procedural region.

Following use, the cable cover is to be removed without contaminating the surface of the cable or the ultrasound machine. Cleaning after use as per the manufacturer's IFU and, depending on the outcome of a risk assessment, high level disinfection with an approved and compatible disinfectant.

The probe/transducer must be cleaned and disinfected as per IFU and risk assessment, regardless of the use of sheath/cover. A risk assessment should determine the level of disinfection required.

After cleaning, all transducers must be stored in an appropriate environment to protect from environmental contamination. It is recommended that a specific cabinet is used, but if this is not available, the minimum standard recommended is a clean disposable cover applied to the transducer to mitigate risks from environmental contaminants.

Records of reprocessing must be kept in accordance with the requirements specified in AS 5369:2023 and manufacturers IFU to ensure a system of traceability is in place to enable recall procedures to be followed in case of decontamination failure.

11.17 Light based disinfection systems for use with ultrasound probes

Light based disinfection systems (LBDS) are listed on the Australian Register of Therapeutics Goods (ARTG) as [Class IIB medical devices](#). Before purchasing light-based disinfection systems for ultrasound probes, the below risk assessment in table 49 is recommended.

Table 49 LBDS risk assessment checklist for use with ultrasound probes

No.	Item	Yes	No	N/A
1	The manufacturer provides device (for example, ultrasound probe) specific IFU	☐	☐	☐
2	Determination if the device is compatible with the light-based disinfection system (LBDS)	☐	☐	☐
3	Determination if the LBDS is registered with TGA	☐	☐	☐
4	LBDS is validated to comply with AS 5369:2023	☐	☐	☐
5	Will this system provide the correct Spaulding classification level reprocessing for the ultrasound?	☐	☐	☐
6	Has the risk versus benefit been determined for patient safety?	☐	☐	☐
7	The manufacturer of LBDS provides evidence for microbial reduction/antimicrobial efficacy	☐	☐	☐
8	Determination of any treatment of RMD that is required prior to exposure to the process to ensure its effectiveness	☐	☐	☐
9	Determination of any restrictions or limitations relating to the size, mass, configuration, or loading orientation of RMDs being processed	☐	☐	☐
10	Review has been conducted of current evidence related to the light-based disinfection systems	☐	☐	☐
11	Risk assessment of physical location for the LBDS to determine reprocessing workflow, storage requirements and maintenance	☐	☐	☐
12	Determination on how the ultrasound probes will be tracked, location of the record storage and in the patients record	☐	☐	☐
13	Documented procedure for reprocessing, including PPE requirements	☐	☐	☐
14	Approval has been obtained to purchase and use the LBDS by local infection prevention and control team, sterilising manager and local procurement	☐	☐	☐
15	Program has been established for staff training and competency assessment for reprocessing ultrasounds	☐	☐	☐

16	Does this improve the current system for reprocessing of ultrasounds?	☐	☐	☐
17	Will there be additional consumables and costs associated with using this system?	☐	☐	☐
18	Will the routine monitoring included in the purchase contract and a person is identified to have responsibility for completing and documenting this?	☐	☐	☐
19	Will using this system impact on any other workflow or service provision?	☐	☐	☐

11.18 Endoscope reprocessing

There are two main types of endoscopes, rigid and flexible.

Rigid endoscopes are made of metal tubes which contain the lenses, and the light channel(s) and are available in a large range of external diameters. These mainly enter the sterile tissues and organs of the human body directly or via a surgical incision, such as laparoscope, thoracoscope, arthroscope, intervertebral disc mirror, and ventriculoscope.

Flexible endoscopes are an optic reusable or disposable medical device that transmit light and carry images back to the proceduralist through flexible transparent fibres. They are used to inspect, monitor and treat interior portions of the body.

Types of flexible endoscopes

Different endoscope types and models have features in common and important differences that need to be considered for them to be cleaned correctly or appropriately. Examples are shown in the below table.

Table 50 Examples of non-channelled and channelled endoscopes

Non-channelled flexible endoscopes	Channelled flexible endoscopes
Nasendoscope	Gastroscope
Transoesophageal Probe (TOE)	Colonoscope
Some Bronchoscopes	Bronchoscope
Some flexible brachytherapy scopes	Cystoscope
	Ureteroscope
	Duodenoscope

Contaminated endoscopes with pathogenic organisms have the potential to transmit microorganisms in three different ways:

- patient to patient from contaminated endoscopes and accessories
- contaminated endoscopes and accessories to the healthcare environment and equipment
- contaminated healthcare environment and equipment to health workers and patients.

Accurate reprocessing of endoscopes and accessories is critical for patient safety, maintenance of the integrity of the scope and prevention of contamination. It is essential that a comprehensive reprocessing, transport, storage and health worker competency gap analysis and/or risk

assessment is conducted on a regular basis and when a significant incident occurs (Chang et al., 2024).

Each endoscopic reprocessing unit requires detailed and easy to understand documented procedures for each step of the endoscope reprocessing program from pre-cleaning to storage and maintenance as per the AS 5369:2023, [Gastroenterological Society of Australia \(GESA\)](#) and manufacturer's instruction for use (IFU).

Education and training

Health Organisations are to ensure that health workers reprocessing endoscopes can consistently demonstrate accountability and responsibility during all stages of reprocessing. Onsite training with experienced and competent staff to be available during onboarding, prior to assessment of competency and in response to incidents. Competency assessment should include information listed in the below table.

Table 51 Sample competency assessment for pre-cleaning

Minimal training undertaken	• Perform bedside pre-cleaning. Flush the endoscope with approved chemical and water, until it is clear with water • Clean outside of the scope • Place in transport container with appropriate identification that it is contaminated • Transport to the designated area where it will be reprocessed • Complete tracking information • Note any issues with the scope, for example, damage, blockage
Training undertaken but competency not completed	• As above plus: ○ perform leak testing ○ clean and brush ○ complete tracking information ○ place in designated area
Training and competency completed	• As above plus: ○ place in Automated Flexible Endoscope Reprocessor (AFER) for high level disinfection ○ complete tracking information

The competency assessment should also include:

- donning and doffing of personal protective equipment appropriate for the task
- hand hygiene compliance as per the NHHI hand hygiene requirements
- selection and use of chemical compatible to the scope
- understanding of scope type, design (biopsy/suction, air, water, auxiliary water and elevator).

Pre-cleaning

Pre-cleaning begins immediately after the endoscopic procedure and before the scope is disconnected from the power source. Pre-cleaning is a two-step process:

- wet wiping the external surface of the scope with a lint free cloth/surgical sponge with an enzymatic/biofilm remover to remove any organic matter before it dries

- suctioning of the working channels using no less than 300mls of water and enzymatic/biofilm solution as per the manufacturer's IFU.

On completion of the pre bedside clean, the used scope is disconnected from the endoscopic power source and:

- remove from the point of care
- place into a transport tray/container to avoid damage to the scope
- allow the scope to coil in relaxed loops with the manual controls facing up
- avoid placing/resting the fixed hard components of the scope directly on the flexible components
- cover, clearly identifying the scope is contaminated
- transport to the reprocessing area.

The method of transport between the procedure and reprocessing rooms must reduce the risk of scope cross contamination.

Leak testing and visual inspection

For endoscopes that require a leak test, it detects any damage to the interior or exterior of the scope. Leak testing must be completed before further cleaning of the scope occurs. Manual leak testing is no longer required if AFER performs leak testing as part of its cycle. Manufacturer's instructions must be followed on how to perform the leak test including how to:

- check the leak tester is functioning
- confirm removal of valves/buttons/caps from the scope
- attach the leak tester to the scope
- angulate the scope
- amount of water required for the scope to be leak tested
- identify if there is a leak
- length of time to depressurise the scope following the leak test.

Manual or automated cleaning

Automated cleaning is using an Automated Flexible Endoscope Reprocessor (AFER) is recommended as the optimal process. Manual cleaning is performed by hand by removing biological material from endoscopes. Brushing of the channels is highly recommended regardless of the use of AFER. The AFER manufacturer's instructions for use (IFU) must be followed before connecting the endoscope and beginning the cycle. When not using an AFER with automated cleaning, manual cleaning including brushing and flushing of channels and ports consistent with the manufacturer's IFU is required before HLD or sterilization.

Endoscopic disinfection and sterilization options

The decision to use high level disinfection or sterilization methods will be dependent on the manufacturer's IFU for each type of scope. The common recommended method is high level disinfection for most scopes. Chemicals used for each step for the cleaning process must meet the requirements articulated within the Therapeutics Goods Administration (TGA) regulation of disinfectants and sterilant.

At completion of the cycle, check that cycle parameters have been met, and all channel adaptors are still connected.

Transport of endoscopes

The type of container system or method for transport of reusable scopes must be evaluated to ensure that cross contamination does not occur.

The principles for transporting reprocessed scope(s) include:

- perform hand hygiene prior to handling a reprocessed scope(s)
- clean reusable lined container or trolley
- disposable or rigid container that enables the scope to be coiled into large loops
- includes any required attachments or accessories
- clearly identifiable as 'clean'
- use of a sterile drape if required.

Storage of endoscopes

The purpose of storing endoscopes is to minimise contamination and protect them from damage. The length of time that a processed scope can be safely stored and maintained in a patient ready state is reliant on:

- accurate and validated reprocessing that meets the required parameters
- drying of scopes (internal and external)
- cleanliness and maintenance of the storage cabinet/cupboard
- storage parameters and of sufficient height, width, and depth to allow scopes to be stored either vertically or horizontally
- risk of contamination, for example, tips of scopes sitting on floor of storage cabinet/cupboard is stored vertically
- microbiological sampling results over time
- handling by health workers.

Documentation

Documentation (electronic or manual) for storage should include:

- 'time in' (date and time)
- 'time out' (date and time)
- print out from endoscope storage cabinet (if relevant).

Tracking is a real-time process of documenting all scope reprocessing stages through to clinical use on a specific patient. Tracing is following steps to uncover and understand the actions along its way. It is either the monitoring of the process (auditing) or examining the process for errors due to an incident.

Documentation for tracking endoscope reprocessing will likely be obtained from multiple sources and may be stored in a combination of paper and electronic systems. Some commercial tracking systems permit input from various systems.

Documentation also includes use of an incident reporting system to record any reprocessing incidents that involve endoscopes, accessories or associated equipment.

Microbiological surveillance

Microbiological surveillance of channelled endoscopes and the Automated Flexible Endoscope Reprocessor (AFER) are a quality control measure or verification of the effectiveness in cleaning, high level disinfection or sterilization and the structural integrity of the channels within a scope. It provides an outcome measure for reprocessing and can assist in identifying unrecognised or undetectable damage.

Collection of microbiological samples requires an aseptic technique and health workers are to be suitably trained to undertake this task. For more information refer to [GESA Infection prevention and control in Endoscopy 2025](#).

Testing of loan scopes

The GENCA guidance requires that loan scopes are to be tested within 72 hours of receipt of the instrument to the organisation (Genca, 2025). All endoscopes returning from servicing or received on loan are to be cleaned and disinfected before use. Endoscopes can be used after cleaning and disinfection and do not need to be quarantined while awaiting microbiological surveillance test results (Genca, 2025).

11.19 Management of endoscopic tube shaft Instruments

Endoscopic tube shaft instruments are used in minimally invasive surgery to grasp, cut, dissect and coagulate tissue and organs, as well as for pinching off vessels. The device has a reusable part that can be removed for cleaning (tube shaft). This part is not necessarily allocated to one device but can be shared between endoscopes. As with many endoscopes these devices have complex designs that require meticulous management throughout the reprocessing process. Inappropriate handling of the device and specific parts may lead to reduction of durability or damage.

There is a risk that a damaged tube shaft may go unnoticed during reprocessing and final check. This could result in the use of damaged instruments, leading to broken parts dislodging during (intra-cavity) patient procedures. Damage may go undetected if the required cleaning and disinfection processes, including checks and validation, are not adhered to.

Product instructions for use (IFU) provide clear guidelines for life expectancy, reprocessing and testing requirements.

Health Organisations using these devices are to ensure that reprocessing of the endoscopic tube shaft instrument is in accordance with both their manufacturer's instructions and *AS 5369:2023 Reprocessing of Reusable Medical Devices in Health Service Organizations*.

All devices must be inspected visually and functionally during cleaning, packaging and prior to each use. Use of any damaged or faulty equipment should be discontinued immediately.

Functional test includes:

- correct assembly
- fulfilment of predefined function
- absence of damage.

Reprocessing steps should include cleaning, disinfection/sterilization, inspection and assembly, testing (electrosurgery insulation testing full length of sheath with particular focus on tip of sheath) and packaging.

Health Organisations are to provide education and training to relevant health workers in reprocessing, use and visual inspection/checks of endoscopic tube shafts as outlined in the product IFU.

11.20 Use of impregnated chemical disinfectant wipe systems

Health Organisations are to exercise caution when using 'ready-to-use' disinfectant wipes (also known as pre-impregnated disinfectant wipe) with active ingredients such as isopropyl alcohol, chlorhexidine gluconate, chlorine dioxide and dimethyl oxazolidine, for high-level disinfection of non-lumened/non channelled RMDs.

These systems are not intended for use on critical medical devices which must be sterilised prior to use on a patient.

Unlike automated reprocessing systems which have a measured dosage of chemistry and a validated reprocess cycle, impregnated chemical disinfectant wipe systems rely on the manual (human) process of applying each wipe in the recommended sequence. This assumes that each part of the device has been in contact consistently for the specified period. The devices for which impregnated chemical disinfectant wipe systems are intended are not easily stabilised aseptically, which makes it very difficult to ensure and verify that all parts of the device have been contacted by the disinfecting agent consistently at the required concentration for the required time (Kühnel and Gühne, 2024).

Most chemical disinfectant wipe systems rely on:

- manual activation of enzymatic cleaner within the disinfectant wipes
- ensuring that all areas of the RMD have contact with active agent within the wipe
- manual tracking of the reprocessing process
- ongoing education and training requirements of health workers conducting high level disinfection
- adequate record keeping and frequency of competency assessment
- health worker vigilance on manual process with cleaning and disinfection with potential for contamination risk post cleaning.

Health Organisations deciding to use impregnated chemical disinfectant wipe systems are to consider the following to minimising risks to patients:

- a risk assessment should be conducted to ensure that there is no alternative reprocessing system available or suitable for this specific RMD
- ensure and verify that impregnated chemical disinfectant wipe systems are not used in any situation where an RMD is required to be sterile for an invasive procedure
- evaluate if there are alternative reprocessing systems for which adherence to best practice standards can be more readily ensured and verified
- ensure and verify that use of an impregnated chemical disinfectant wipe system is in accordance with the RMD's manufacturer's instructions
- ensure health workers are trained and competent in the use of the system and adhere to relevant NSW policies
- ensure that impregnated chemical disinfectant wipe systems' manufacturer's instructions for use are strictly adhered to
- ensure that all surfaces are cleaned and adequate contact made with the active chemical for the appropriate time.

11.21 Use of fume or vapour soaking stations

Engineering controls are physical in nature, including mechanical devices or processes that eliminate or minimise the generation of chemicals fumes, suppress or contain chemicals, or limit the area of contamination in the event of spills and leaks. Ventilation is a means of maintaining a safe atmosphere by the introduction or recirculation of air; by natural, forced or mechanical means. Maintaining a safe atmosphere in the storage and handling area of hazardous chemicals is an important control measure to ensure health worker safety ([Managing risks of hazardous chemicals in the workplace Code of Practice, 2020, Safe work Australia](#)).

Fume or vapour soaking stations facilitate the immersion of reusable medical devices such as flexible endoscopes and/or sonographic devices to bring them into contact with a liquid chemical disinfectant.

The high-level disinfection occurs through the action of the active ingredient. The fume or vapour soaking stations provide a receptacle to soak the device and remove the fumes and vapours. Manufacturers' instructions for the use of the fume or vapour soaking station and the active ingredient must be followed, as well as any relevant Work Health and Safety instructions.

Fume/vapour soaking stations are not listed on the Australian Register of Therapeutic Goods (ARTG) as the Therapeutic Goods Administration (TGA) does not consider them to be medical devices.

Steps for minimising risk when using fume/vapour soaking stations

Health Organisations are to review their facilities' use of fume or vapour soaking stations.

Where fume or vapour soaking stations are used, Health Organisations are to ensure that systems and procedures are in place to:

- selecting areas suitable to maintain dirty to clean flow
- adequate training and PPE availability
- SOPs for handling, soaking, and rinsing reusable devices, including soak times, concentration of chemicals and rinsing
- monitor that they are used in accordance with their manufacturer's instructions for use
- monitor their performance.

11.22 Infant feeding equipment

Before use by another baby, reusable baby bottles, teats and caps must be cleaned and thermally disinfected in accordance with the manufacturer's IFU.

Breast feeding equipment, such as breast pump components, must be cleaned and sterilised between patients. A designated cleaning space should be allocated to minimise cross infection of prep areas and equipment reprocessing.

Health Organisations are to ensure that these items are reprocessed as per the IFU within the given parameters, at a minimum, as per the AS 5369:2023. In situations where the IFU acknowledges the variation in jurisdictional requirements, the local facility should follow AS 5369:2023 requirements.

Chemical disinfection must only be used on equipment that is designated to and reused by one baby.

Prior to transfer, health workers should provide guidance to parents or carers about cleaning and disinfecting feeding equipment that is appropriate for the home setting.

11.23 Cleaning and disinfection of heater cooler devices

A Health Organisation should employ infection prevention and control strategies to minimise the risk of non-tuberculous *Mycobacterium* (NTM) infection associated with heater-cooler devices (HCDs) and other relevant devices.

Heater-cooler devices contain water tanks that regulate temperature during procedures. Although this water does not come into direct contact with the patient, it can become contaminated with NTM. During operation, tiny airborne particles can be released from the device's internal components, especially the water tanks. These aerosols may carry NTM and disperse into the operating room environment, posing a risk of infection to patients undergoing surgery.

Health Organisations should have a designated person responsible for coordinating management and response to device related infection. At a minimum, the following should be in place where an HCD is in use:

- Adhere to all maintenance, cleaning and disinfection according to manufacturer's instructions for use (IFU)
- Routine testing and maintenance of HCD
- Ensure systems for maintaining records of testing, maintenance and use are in place
- Process for management of HCDs that are sent overseas for repair
- Use ventilation systems or exhaust tubing to direct any aerosol emissions away from the sterile
- Identify and test relevant equipment
- Ensure the results of confirmed device contamination are reported to the TGA, the manufacturer of the device, and NSW Health
- Establish policies and procedures to minimise exposure risk to patients, and to enable service continuity
- Communicate potential risks and local response strategies to senior management, relevant clinicians, and primary health providers. This may include the hospital executive as well as infection prevention and control, infectious diseases, cardiac surgery, perfusion, anesthesia, clinical microbiology, anatomical pathology services and patients.

For more information on identification of a positive result *M chimaera* from a heater cooler device refer to NSW Health [Mycobacterium chimaera and open-heart cardiac surgery](#).

11.24 Stethoscopes

Auscultation of the heart, lungs, abdomen, and major arteries with a stethoscope has long been considered an integral part of the physical examination and most clinicians prefer to use their own stethoscope. Evidence suggests that stethoscopes are potential vectors for microorganism transmission between patients (Jovanovic et al., 2024, Messina et al., 2018). *S. aureus* has been identified surviving on earpieces of stethoscopes for longer than 18 hours.

All parts of the stethoscope that have been in direct contact with skin (patient's or clinician's) should be cleaned with a neutral detergent, at minimum, before reuse.

In extreme risk clinical areas, or during outbreaks, health workers should consider cleaning and disinfection of reusable stethoscopes or using disposable stethoscopes.

11.25 Toys

Toys are potential vectors for fomite transmission and are reservoirs for microorganisms. Toys and items that are handled or placed in children's mouths or used in baths are to be washable, quick drying and easy to clean. Health Organisations are not to purchase or encourage the use of water-retaining bath toys, non-washable soft toys and other toys which are difficult to clean. If such toys are brought into the Health Organisation by the patient or their visitors, use should be limited to a single patient only.

Used toys and therapeutic aids should be cleaned between each patient with a neutral detergent. Health Organisations are to purchase products that can be cleanable and withstand disinfection if necessary.

If toys or therapy items become contaminated with body substance including saliva, by actions such as sneezing or putting into a child's mouth, remove from use until washed in warm water and detergent and dry. Should it be required, dry cleaning instructions for the toy should be discussed with the patient and/or carer. If a toy cannot be cleaned it should be discarded.

Soft toys should not be permitted in a communal area unless the toy is being used as a therapeutic aid for an individual patient. Clinicians who use soft or otherwise 'difficult to clean' toys as therapeutic aids should consult with local infection prevention and control team and undertake a documented risk assessment for the selection, maintenance and cleaning of these items. For more information refer to the ACSHQC guidance on [Safe management and use of shared toys and play therapy equipment in healthcare settings](#).

11.26 Cleaning and reprocessing of items used in community and home settings

Any reusable item used between patients/clients must be cleaned with a neutral detergent at minimum in between use and disinfected as per the IFU if necessary.

The following practices are recommended regarding cleaning and reprocessing of reusable portable equipment in community and home settings:

- A risk assessment for selection of portable items is to be undertaken by the health worker
- Portable reusable materials and equipment, for example, equipment bags, weight scale, chair pads, examination mattresses, laptops or IV volumetric pump/pole, used in the provision of patient care are to be:
 - able to be cleaned
 - routinely cleaned at regular intervals in accordance with manufacturer's IFU and/or health service recommendations
 - cleaned after use and between patients
 - removed from use if worn or damaged.

Other Considerations

Health workers are encouraged:

- not to take unnecessary equipment into the area
- to use a protective sheet between the equipment
- to clean and, if necessary, disinfect equipment on removal from the room.

Equipment provided to clients for use at home, for example, commodes, chairs, heel protectors, pressure relieving cushions, are to be:

- non-porous, fluid resistant and able to be washed
- single patient use (if unable to be washed).

The Health Organisation is to have a program for ensuring that loaned equipment is cleaned and, if necessary, disinfected when it is returned from a client's home.

Reusable equipment that can be reprocessed must be reprocessed in accordance with the manufacturer's IFU and local policy.

11.27 Transport of RMDs and equipment

A reprocessed RMD should be handled and transported in a manner which minimises the risk of contamination. This includes:

- placing the reprocessed reusable medical device into a protective barrier system (PBS) prior to transport
- using transport containers that are:
 - designated for that purpose only and clearly labelled
 - rigid, robust, and leak-proof
 - adequate in size to hold items securely and safely, protecting their integrity until point of use
 - able to be cleaned regularly and disposed of and replaced when no longer serviceable
 - able to be sealed or locked, such as tamperproof
- dedicating sterile transport containers for the transport of reprocessed RMDs only
- transporting the reprocessed RMD in a fully enclosed or covered trolley
- labelling transport containers clearly to prevent transport errors, clean/dirty segregation, and safe handling practices.

Before transport occurs, a risk assessment should be undertaken to assess the likelihood of contamination and whether additional controls are required to mitigate this risk or an alternative to transporting equipment is required. Appendix B of AS5369:2023 provides guidance on the risk assessment processes to be undertaken.

If transporting contaminated semi-critical or critical RMDs is necessary, the RMDs are to be confined and contained within a single use, leak-proof plastic bag. The bag should then be placed in a rigid reusable container that is secured within the vehicle and separated from the driver's compartment.

Contaminated RMDs/equipment and unused sterile equipment should not be transported in the same container.

Personnel responsible for packaging, transport and the collection of the used RMDs should be trained to do so.

When transporting reprocessed RMDs the following items should be considered:

- where possible, temperature and humidity monitoring of sterile stock while in transit is recommended including maintaining records of the information. For short transport a climate-controlled vehicle is recommended
- mechanical cleaning of all the transport containers after transport of dirty items and before transportation of sterile stock
- external labelling of container and securing methods to prevent unauthorised access to contents

- minimum requirements for the fit out of transport vehicles, such as physical separation of sterile and dirty stock
- transport vehicle guideline regarding breaches in parameters in transit/in the event of an accident where stock has been compromised.

Where problems have been encountered during transport and storage of a reprocessed and released RMD recall and risk assessment of the RMD is necessary.

11.28 Stock room for RMDs/sterile equipment or consumables

Sterile items including RMDs sterilized in the healthcare facility including oral health and sterile items produced from commercial suppliers shall be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source.

The planning of stock storage areas and systems is integral in ensuring efficiency and that the sterile stock maintains its integrity, is fit for purpose and safe for patient use. The storage area should have suitable materials with smooth finishes, water resistant and robust enough to withstand frequent cleaning. Lighting should be fitted flush into ceiling to reduce dust entrapment.

Within the perioperative environment equipment that is purchased as sterile, or RMDs that have been reprocessed, must be stored in a way that:

- maintains the level of sterility or reprocessing (for example, sterile, high or low-level disinfection)
- maintains the integrity of equipment packaging and ensures that the equipment and its packaging are protected from damage by sharp objects, repetitive handling or other physical movement, for example, consider the use of protective packaging or barrier systems or a sealed cabinet
- prevents contamination, damage and environmental exposure, including:
 - temperature controlled within the range of 18°C to 25°C, or otherwise specified by the equipment manufacturer
 - relative humidity controlled within the range of 35% to 70%, or otherwise specified by the equipment manufacturer
 - controls to prevent exposure to light, dust and moisture, including managing risks associated with water source
 - implementing controls other than traps or chemicals to prevent contamination by vermin, as these measures may damage or contaminate sterile stock and reprocessed RMDs
- ensures adequate ventilation of the storage area that is based on a risk assessment of the space, and includes:
 - controlling ventilation to prevent build-up of humid or stagnant air
 - avoiding storage under air inlet or outlet vents
 - maintaining ventilation continuously at positive pressure to all adjoining areas.

Other strategies that Health Organisations can employ to ensure adequate storage of sterile medical devices, or RMDs that have been reprocessed, include:

- restricting access to storage areas
- providing dedicated storage areas for these equipment
- ensuring segregation of any dirty activities or contaminated items away from storage areas
- ensuring these storage areas are included in routine cleaning schedules
- promoting and enabling hand hygiene prior to the handling of stored items (such as, providing hand hygiene facilities near storage areas).

In areas where commercially purchased sterile equipment is stored, contents from external cardboard boxes must be decanted outside of the storage area. Protective inner boxes (for example, dispenser boxes) may be required to be stored in the storage area to protect the integrity of single use sterile items.

Do not use cardboard boxes (transport or outer packing) including corrugated cardboard carton as routine storage. Items should be removed from outer packaging material but not to be removed from inner primary packaging even if it is in cardboard box to reduce direct handling of consumables. Bulk storage area should be located on the periphery of the unit so that deliveries of commercially prepared sterile stock is de-boxed from outer store/transportation packaging before being brought into the sterile stock storage area. Space is needed to unpack cartons. Where consumables may only have a primary packaging layer, the storage of these items should be managed based on risk assessment.

Access to the storage area(s) for reprocessed RMDs should be restricted to individuals that have been trained and deemed competent in the handling of these devices, with restricted access for authorised personnel signage clearly displayed.

AS5369:2023 provides additional guidance on the storage requirements for reprocessed RMDs; it does not provide guidance on the storage requirements for commercially purchased sterile equipment or medical devices that are intended for single use only. Additionally, [GENCA Infection prevention and control in Endoscopy 2025](#) provides specific guidance on the storage of reprocessed endoscopes.

Storage of RMDs in clinical areas including peri-operative environment

Reprocessed RMDs need to be stored in a manner that maintains integrity of the sterile barrier system and minimises the risk of environmental contamination. This can be achieved by providing dedicated storage areas of reprocessed RMDs that have been released for use, including:

- dedicated rooms that have walls, floors and ceilings which are continuous, smooth, impervious, and easy to clean
- joins and hard-to-clean corners must be avoided or minimised where possible
- surfaces that are well maintained (such as, are clean, dry, and dust-free)
- sterile storage area is not to be used as a shared equipment storage space (for example, wheelchairs)
- sterile stock storage areas must be designed and constructed to prevent any risk of contact between sterile items and water
- in storage areas, temperatures should be controlled and maintained to ensure supplies are protected from direct sunlight
- sterile RMD and sterile consumables should be stored on or in designated shelving or containers
- RMDs must be handled in a manner that does not cause contamination of the contents or damage to the sterile barrier system
- sterile store areas must be regularly cleaned to a routine, documented schedule
- if the packaging of a sterile item becomes compromised by moisture or damage, the stock must be considered unsterile
- if unsterile stock cannot be reprocessed, stock should be disposed of immediately. If unsterile stock can be reprocessed, the stock should be repackaged and reprocessed again before use
- decision to use or dispose of the items after a potential contamination event should be based on risk rating and the potential level of contamination

- the Health Organisation is responsible for ensuring that a stock rotation procedure and policy is in place. Stock levels should be maintained to meet the needs of the clinical area while not compromising stock sterility or wastage
- the method of transport should also be assessed to ensure delivery occurs in a safe and clean manner
- semi-critical items should be stored appropriately to prevent environmental contamination. All endoscopic instruments (except those in sterile packaging) should be stored in an appropriate cabinet or reprocessed within set timeframes prior to use.

Shelving, including compactors, used to store sterile stock and reprocessed RMDs should meet the following criteria:

- be constructed from robust, non-shedding materials that are easy to clean and maintain. The use of metal open wire shelving/racks or alternative plastic/polypropylene baskets with perforated bases is recommended. Solid-based storage containers are prone to dust collection and require significant cleaning resources to maintain in a clean dust free state, which can lead to increased sterile stock handling and the potential for increased environmental contamination
- has smooth surfaces, to avoid damaging items and packaging
- has a top shelf that is at least 520mm below the ceiling to meet requirements for fire sprinkler systems (AS2118.1) and is no higher than 1700mm from the ground to enable safe work practices (AusHFG)
- has a bottom shelf that is at least 250mm above the floor for fixed shelving (AusHFG) or 150mm above the floor for non-fixed shelving (AusHFG), to minimise the risk of damage and contamination during floor cleaning processes as it is easier to clean underneath higher mounted shelving
- avoid contact with other room fixtures, such as windows, to prevent contamination and environmental exposure
- support safe handling and work health and safety practices, such as consideration of the height of shelving and accessibility to stock.

11.29 Event-related sterility

The shelf-life of a packaged sterile item is event-related and depends on the quality of the sterile barrier system (wrap, pouch and container), the storage conditions, conditions during transport, and the amount of handling.

Certain events compromise the sterility of a package. These events include multiple handlings, moisture penetration, and exposure to airborne contaminants, all of which can compromise the integrity of the packaging and seal and allow contaminants to enter the packaging.

[Association for the Advancement of Medical Instrumentation \(AAMI\) ST79 Section 10.3.3](#) states that event-related dating can be used unless the product has an identifiable expiration date because of the degradation of the product based on information from the device manufacturer. The wraps and pouches manufacturer should provide evidence to confirm the duration of product integrity and product specific expiry date and the IFU should be referenced as per AS 5369:2023.

To effectively implement event-related sterility, healthcare organisations must manage the handling of sterile items from the moment they are removed from the sterilizer through transportation, storage, and eventual patient use. Health Organisations are to have:

- Written procedures for how shelf-life is determined, and risk assessment approach should be applied in the event of a potential breach
- Process in place to ensure that sterile stock is stored according to the date of manufacture, with older stock to be used first

- Inspect all sterile items prior to use to ensure the integrity of the packaging, chemical indicator change, and condition of the item
- Return compromised sterile items to the appropriate personnel so that protocols related to the management of these items may be implemented.

Refer to figure 25 as a guide to determine the event related sterility of an item.

Figure 25 Event related sterility risk assessment



Risk assessment in the event of sterility compromise in non-perioperative environment

In the event of potential contamination within the sterile stock areas/room due to breakdown or issue with air/traffic movement, location, humidity, insects, vermin, flooding of the storage area, open/closed shelving, the facility should perform a risk assessment to identify all the risks. The risk assessment should include:

- the condition of walls, hard surfaces and shelving units
- the condition of the storage containers for moisture pooling, dust or dirt
- microbial barrier properties of the packages, if packages are heat-sealed in impervious plastic and the seal is intact or not (qualified packaging protects its contents from adverse environmental conditions, including therein variations of temperature and room humidity).

Temperature and humidity controls are designed to maintain a suitable environment that reduces risk of microbial growth. An intact sterile barrier system should protect the contents from microbial contamination during temperatures and humidity outside acceptable ranges for a short period of time. An isolated incident or breach will need to be risk assessed however ongoing and sustained breaches increase the overall risk and potential impact. There is limited evidence that connects breaches of temperatures or humidity directly to the sterility of contents with an intact sterile barrier system. Inspection and risk assessment is recommended to determine quality status of items within the sterile stock area.

In the event of humidity or temperature concerns in the sterile stock area the Health Organisation should conduct a risk assessment to assure the sterility of the stock (event related sterility principles apply; refer figure 25):

- identify all the risks within the sterile stock area/s
- check walls, hard surfaces and storage containers with lots and/or laminates for moisture pooling
- check packages for soiling, wetness and moisture
- isolate potential contaminated items for further review
- where no compromise identified and items released for use, health workers should be reminded of responsibilities to check sterility during set up and escalate as required
- where the above occurs; additional inspection of sterile stock areas should be conducted
- where items have been deemed compromised; discard or reprocess
- write a brief report with your recommendations on non-conformance of the item and the resultant outcome
- document and escalate the findings to relevant executive representatives for further decision making.

Any issue that compromises sterile stock during transport or storage should have a similar risk assessment and escalation process. Refer to Appendix 11A for more information on risk assessment and escalation of temperature or humidity variation in perioperative and sterile stock environments.

Appendix 11A Risk assessment and escalation of temperature or humidity variation in perioperative and sterile stock environments

Background

Published data on the impact of relative humidity on bacterial and fungal growth in healthcare is limited. The majority of publications appear to be either related to the food industry or buildings, particularly for fungi (Wolkoff et al., 2021). Many bacterial pathogens have longer survival times with higher relative humidity, and fungal growth is increased.

When it comes to healthcare environments, ideally, the temperature range within the operating environment will vary in different locations (refer to table 52). Individual operating rooms should have a temperature range of between 20°C and 22°C; this temperature range inhibits bacterial growth and is tolerated well by patients and health workers ([ASHRAE 2019 Humidity Control Events in Perioperative Care Areas](#)). However, the temperature may require adjusting to accommodate some types of surgery or the condition of individual patients. For example, a higher ambient temperature may be required for burns or paediatric patients, as these patients are highly susceptible to hypothermia. Lower ambient temperatures may be required for some types of neurosurgical procedures (Wan et al., 2011).

Relative humidity (RH) is the amount of water vapor present in air expressed as a percentage of the amount needed for saturation at the same temperature. RH depends on the temperature and pressure of the system of interest. To acutely decrease the RH level of an operating room, either remove water vapor or increase temperature (it is unlikely that one would increase the atmospheric pressure). Cold operating rooms have a higher RH than warm operating rooms with the same absolute humidity.

The RH in the operating room should be maintained at between 50% and 60% to both inhibit microorganism growth (such as fungi and bacteria) and decrease risks associated with static electricity. The RH requirements in other perioperative areas, such as the sterile stock room, is between 35% and 70% and perioperative environment is between 40% and 60% (refer to table 52).

The rationale for the current 30% lower limit is that low RH:

- decreases the shelf-life of certain supplies, such as biological indicators and chemical indicators, used for sterilization monitoring and electrocardiogram electrodes
- increases the chance of electrostatic discharge that could harm or interfere with electromedical equipment (Curless et al., 2021) and potentially spark a fire (this is less of a recent issue because the risk of electrostatic discharge is less with non-flammable anaesthetics and antistatic surgical gowns).

The rationale for the current 60% upper limit is that high RH:

- increases the chance of surface mould and mildew growth
- may increase the risk of wound infections
- is less comfortable for operating room personnel.

It should be noted that there is sparse experimental evidence documenting the exact levels where these risks increase.

Risk identification

The maintenance of recommended temperature and humidity in healthcare environments is necessary to ensure patient and health worker safety and comfort. This is particularly important in specialised areas, such as the operating theatre, perioperative environment, and sterile stock areas where reusable medical devices (RMDs) are stored in bulk. Where heating, ventilation and air

conditioning (HVAC) systems are unable to maintain the recommended temperature and relative humidity, facilities are to have a local risk assessment and escalation process in place to ensure minimal impact to service provision (Kramer et al., 2006, Tang, 2009).

Temperature and humidity variations that persist for extended periods in perioperative areas – including areas where RMDs are stored in bulk – can increase the risk to patient safety through:

- impaired sterility of stock
- operating or service list disruption
- discomfort to health workers, patients and visitors/carers
- environmental contamination
- damage to clinical equipment
- potential increased infection risk to patients
- financial implications
- workforce impact.

Optimising ventilation to reduce respiratory particle transmission and airflows for transmission-based precautions are equally important. Activities in support of those precautions are not covered in this document (refer to [Infection prevention and control in Healthcare Settings PD2023_025](#)).

Risk management

The clinical significance of variations in temperature and humidity can depend on many factors, including the duration of the event, the rapidity of the parameter changes, and the activities that occur in the affected locations.

The operational or functional capacity to fully control variations of inside temperature and humidity ranges may also depend upon HVAC system capacity load and response capability to external weather variations. Decreasing inside temperatures may impact and increase the RH.

In the case of perioperative environmental areas and any locations where bulk RMDs are stored, facility staff need to consider undertaking a risk assessment and develop a local response or trigger plan for activation in the event of variances outside the recommendations.

A risk assessment may be used as evidence that the operational breach had no negative safety consequence and may also be used as a basis for future performance evaluations.

Risk assessment steps

If the relative humidity is below or above 5% or the temperature below or above $\pm 1.5^{\circ}\text{C}$ for the specified period within the operating theatre, sterile stock area where bulk RMDs are stored or perioperative environment on the risk assessment, the individual responsible for monitoring must notify relevant authorities. Escalation and review should occur at the earliest sign of variation ([NHS England 2021 Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises](#)).

The facility must conduct a risk assessment and initiate immediate action plans as per local response and recover plan in consultation with local engineers, sterilization services, clinical professionals, management and infection prevention and control staff.

If unsuccessful in maintaining the recommended parameters in any of these areas continuously for more than 8 hours within any 24-hour period, the incident must be escalated to the highest authority within the facility to define necessary actions.

Table 52 Humidity and temperature thresholds

Area	Relative humidity (%)	Temperature (°C)	Time	Corrective actions
Operating theatre	Upper limit >60 Lower limit <35	Upper limit >22 Lower limit <18	2 hours	Inform facility engineers
Sterile stock area	Upper limit >70 Lower limit <35	Upper limit >25 Lower limit <18	8 hours	Conduct a risk assessment
Perioperative environment*	Upper limit >60 Lower limit <40	Upper limit >25 Lower limit <18	24 hours	Notify hospital management

* Recovery and other supporting spaces.

Reference- [AusHFG B.0190 Sterilising Services and Endoscope Reprocessing Unit](#), Australian College of Perioperative Nurses (ACORN) Standards for Perioperative Nursing in Australia, Australian Standard 5369:2023, Reprocessing of reusable medical devices and other devices in health and non-health related facilities, [NHSW Health Engineering Services Guide](#), [Victorian Health Building Authority Response to humidity control events in sterile store and perioperative areas Health Technical Advice](#), [WHO guidelines for indoor air quality : dampness and mould](#)).

Suggested process or triggers for establishing appropriate humidity and temperature level in the perioperative area

Step 1

Evaluate the history of relative humidity and temperature in the area, where possible. Local facilities in consultation with subject matter experts (such as, HVAC engineers, infection prevention and control, infectious diseases or microbiologists) to agree in the timeframe of the measurements (for example, between 30 and 60 minutes) and the length of time the facility wants to measure.

Step 2

Determine the relative humidity and temperature recommended for the clinical environment.

Step 3

Determine if conflicts exist between history, current parameters and product requirements.

Step 4

Assess the risk to sterile stock and patient care if the parameter variation continues. The following considerations should be given when conducting a risk assessment:

- identification or likely cause of the variation
- the duration of the expected outage and any likely reoccurrence risk (for example, predicted weather patterns and power access)
- the duration and magnitude of the variation in temperature and humidity, if any
- evidence of condensation, dampness, water splashes or water damage
- concern for compromise of equipment function or supply sterility
- the risks profile of the potentially affected supplies
- the manufacturers instruction for use (IFU) regarding supply or medication storage

- the level of gross contamination (for example, for water intrusion, if any)
- the presence or possibility of visible environmental fungi or microorganisms
- the effect on functionality of fixed and mobile equipment.

Step 5

Establish appropriate temperature and humidity level based on risk to sterile stock and patient care.

Additional timeframe considerations

Any humidity and temperature variation outside of the recommended parameters (refer to table 52) should be escalated within a timeframe of between 2 and 8 hours. In the event an immediate rectification is not available, and remains persistent, the following steps should be considered.

In event of high humidity (>60%) for more than 18 consecutive hours

Where there has been a variation and humidity has been determined to be in the upper limit for more than 18 hours:

- promptly assess all surfaces in the room, including walls, floors, furnishings, equipment, and sterile stock, for evidence of visible or tactile dampness
 - if all visible surfaces are dry, locate items most likely to be affected (for example, RMDs and implantable devices)
 - relocate supplies if there are concerns for storage at high humidity levels
 - if any visible dampness is found, do not start any new operative or other invasive procedures until the humidity level no longer causes condensation. An exception may be made to proceed with emergency surgery ideally using surgical supplies from an area unaffected by the humidity event
- all RMDs with evidence of moisture in or on the packaging are to be considered contaminated and should be reprocessed again
- consult with the local infection prevention and control team for additional assessments in conjunction with the perioperative team, and equipment and RMD manufacturers, if relevant
- if condensation is observed during the intraoperative period, notify the surgeon of the potential risk to patient and failure in electrical equipment
- report any patient care that occurred in an area with visible dampness or mould growth as an event in the local incident reporting system
- discard any damaged supplies that cannot be reprocessed and determine if surgical procedure can continue safely
- report any visible dampness and/or mould growth as the event in the incident reporting system.

In event of low humidity (<30%) for more than 18 consecutive hours

Conduct a careful fire prevention risk assessment to identify if there are potential fire ignition hazards including any fuel, ignition, and heat or oxidizer sources. Take appropriate measures to prevent surgical fires, including:

- ensuring alcohol-based skin preparations do not pool and are fully dry before draping
- removing drapes soaked with antiseptic before using potential ignition sources
- seek specialist advice from engineering and fire safety experts in your service.

Following steps are to be taken for high temperature for more than 18 consecutive hours:

- physically inspect all surfaces in the room for humidity and evidence of visible or tactile dampness
- assess supplies and review the manufacturer's IFU to ensure supply performance is not affected by high temperatures for the duration of the event
- relocate stored items likely to be affected by high temperatures
- discard any damaged supplies and conduct risk assessment to determine if operations can continue safely
- report the event in the incident reporting system.

Following steps are to be taken for low temperature for more than 18 consecutive hours:

- review patient status especially those who are vulnerable to unintentional perioperative hypothermia and reschedule if appropriate
- ensure the patient's temperature is monitored upon arrival to the postanesthetic care unit and until normothermia is reestablished
- promptly assess all surfaces in the room, including walls, floors, furnishings, equipment, and sterile stock, for evidence of visible or tactile dampness
- relocate items most likely to be affected by storage at low temperatures
- report the event in the incident reporting system.

Suggested mitigation steps:

In order to prevent any humidity and temperature variation outside of the recommended parameters, the following risk mitigation steps are to be considered:

- the local maintenance team to check and re-set chiller settings, if needed, to accommodate increasing outside temperature
- engage appropriate experts (such as engineers) to analyse the role of energy efficiency strategies that may potentially contributing to increases in temperature +/- humidity
- check ventilation systems in adjacent parts of the hospital to make sure they are not having an impact that the operating theatre ventilation system is trying to compensate for (for example, energy efficiency measures, such as increasing ambient temperatures or decreased the function of air conditioning systems afterhours)
- check air handling system capacity and, where able, increase
- outside air intake is key to ensure sufficient fresh air is available within the theatre. Steps should be taken to condition the outside air entering the operating suite
- consider dehumidification to reduce the humidity. However, these portable items can pose work health and safety issues. Location, placement, and type of dehumidifier are crucial due to potential changes to air flow and impact on sterile field. (note: portable dehumidification devices can pose additional infection risk in the perioperative environment; if used, they must be cleaned, and water trap emptied)
- implement an automatic monitoring system with active alerts when the temperature or humidity thresholds are exceeded, where possible or available. These devices require calibration and maintenance. Consider incorporating signs of condensation into the monthly checklist, particularly in low-risk areas

- establish a built-in process for facilities engineering services staff to perform early investigation and corrective action to restore temperature and humidity to normal parameters
- implement an active internal escalation, notification and response process to relevant stakeholders when out-of-range temperatures or humidity occur and are expected to be prolonged
- implement early decision-making by authorised team to relocate supplies and, when needed, stop procedures in consultation with infection prevention and control, infectious diseases/microbiologist and facilities engineering services.

Table 53 Recommended temperature and relative humidity as per various standards

Standard/guide	Area	Relative humidity range (%)	Temperature range (°C)*
Health Engineering Services Guide:2022	Operating theatres	35 – 60	18 – 27
	Bronchoscopy, endoscopy procedural room	35 – 60	20 – 23
	Sterile stock store operating theatres	35 – 60	20 – 23
AusHFG Part B 0190	Sterile stock store for RMDs	35 – 70**	Not exceed 25
ACORN	Operating theatres	50 – 60	20 – 22
	Sterile stock store	35 – 68	18 – 22
	Perioperative environment	40 – 60	18 – 24
AS 5369:2023	Sterile stock store	35 – 70	18 – 25
ASHRAE (US guideline)	Operating theatres	20 – 60	20 – 24
HTM-03 (UK guideline)	Operating theatres	Floating with max 60%	18 – 25

* Local adjustable $\pm 1^{\circ}\text{C}$ from setpoint

** Many commercial RMDs require <60